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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/009,571

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Neil T Dear

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER

500 W. MADISON STREET

SUITE 3800

CHICAGO, IL 60661

EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/009,571	Applicant(s) DEAR ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 12, 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

Applicants' amendment and Request for Continuing Examination of September 25, 2008, in response to the Final Rejection of this case mailed March 27, 2008, is acknowledged. It is acknowledged that no claims have been cancelled, amended, or added. Claims 1-6 are pending. Claim 6 was previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-5 are hereby reconsidered.

Drawings

Objection to Figure 1 for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:) is maintained; corrections have not been made.

Specification-Objections

Objection to the specification for improper formatting is maintained; corrections have not been made.

Objection to the specification for containing hyperlinks is maintained; corrections have not been made.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Rejection of Claims 1-5 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility, for the reasons set forth in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

Art Unit: 1652

(A) The threshold for utility is low. To be patentable the invention must only have one specific, substantial, and credible utility.

(B) Applicants' assertion of utility creates a presumption of utility unless (A) the logic underlying the assertion is flawed or (B) the facts upon which the assertion is based are inconsistent with the underlying assertion (MPEP 2107.02(III)(B)). The asserted utility for the recited protein, including use as bait for identifying inhibitors selective for CAPN11 and subsequent use of the inhibitors in treatment of disorders associated with CAPN11 activity, are credible.

(C) The Office Action appears to accept that Applicants' assertion that the polypeptide of SEQ ID NO: 2 is a calpain-family protease is credible (pg 6, line 5 in paragraph (B)).

(D) Applicants maintain that the utilities of the claimed invention are specific and substantial. The polypeptides claimed in the invention may be useful, for example, as a bait for identifying substances, which are able to inhibit enzymatic activity of the polypeptide See, specification, page 4, lines 1-21.

Applicants demonstrated that CAPN11 is most strongly expressed in testis. Also, Applicants determined the chromosome on which the human CAPN11 gene is located. Because it is known that calpains in other tissues are involved in certain processes, such as germ cell apoptosis and regulation of tissue-specific transcription factors, it is reasonable to suggest that CAPN11 may be involved in similar processes in testis.

These utilities are specific and substantial. It is not as if Applicants are claiming that polynucleotides or polypeptides might be useful in treating unspecified disorders, or that the

Art Unit: 1652

protein has unspecified useful properties. In contrast, the application discloses a relation to specific processes, such as germ cell apoptosis. A person skilled in the art knows that cysteine proteases and calpains are involved in apoptosis.

The use of the invention to advance treatment of the specified disease (for example, male infertility) is providing a public benefit. Moreover, Applicants respectfully maintain that the use of inhibitors of CAPN11 activity to treat infertility inherently demonstrates utility for the protein CAPN11 itself.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: This is the same argument provide in the prior response. Applicants are directed to the prior action, (A).

(B) Reply: This is the same argument provide in the prior response. Applicants are directed to the prior action, (B).

(C) Reply: It is acknowledged that Office Action accepts that Applicants' assertion that the polypeptide of SEQ ID NO: 2 is a calpain-family protease is, more likely than not, credible. However, as explained in the prior actions, said assertion is not an assertion of a specific and substantial utility.

(D) Reply: Regarding use as bait, see the prior action, under response (C).

Regarding CAPN11 being expressed in testis, see the action of January 12, 2007, under response (A).

Regarding determination of the chromosome on which the human CAPN11 gene is located, see the prior action, under response (C).

Art Unit: 1652

Regarding Applicants argument that they are not are claiming that polynucleotides or polypeptides might be useful in treating unspecified disorders and that the protein has useful properties related to germ cell apoptosis, see the prior action, under response (C).

Regarding use of an invention to advance treatment of male infertility, it is acknowledged that such an invention would provide a public benefit. However, the instant application does not provide evidence that CAPN11 can be used to treat male infertility. See the action of January 12, 2007, under response (C).

Applicants' responses to the Office's prior rebuttals.

Regarding Applicants' arguments under (A)-(C) and (E)-(I), all said arguments have been previously presented. Applicants are referred to the Actions of August 8, 2006, January 12, 2007, June 1, 2007, November 14, 2007, and August 22, 2008 to re-review the Office's reasons for why said arguments are not persuasive.

Applicants' argument of (D): It is well within a skill in the art to arrive at substrates and design proper assay conditions. Applicants' position is that the application's disclosure is sufficient to enable a skilled artisan to identify an inhibitor of CAPN11 activity. Applicants respectfully point out that claims do not recite treatment of diseases; accordingly, Applicants are not required to demonstrate that treatment of diseases is enabled under §112 standard.

This argument is not found to be persuasive for the following reasons. It is acknowledged that assays for detecting the activity of many proteases are known. However, the testing and screening of an essentially unlimited number compounds, as possible substrates, wherein the assay to be used is not disclosed by the application or the prior art represents undue experimentation. Likewise, use of any identified substrate and assay for further identification of

Art Unit: 1652

a CAPN11 inhibitor represents further undue experimentation. In addition, there is no expectation of success in identifying a CAPN11 substrate, or inhibitor, or that identification of a substrate, or inhibitor, will provide a real-world use for Applicants' CAPN11 protein. Most importantly, issuance of a patent must be based on Applicants' discovery and disclosure of a utility for CAPN11. Such discovery is not disclosed in the instant application. Applicants have merely asserted that their protein has the function of any calpain protein, a large and diverse genus of proteins, and left to the public the job of determining the specific function.

For these reasons and those explained in the prior action, rejection of Claims 1-5 under 35 U.S.C. 101/112 because the claimed invention lacks a substantial and specific utility is maintained.

Written Description

Rejection of Claims 4 and 5 under 35 U.S.C. 112, first paragraph/written description, as described in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following argument.

The specification (page 4) clearly discloses that CAPN11 is a calcium-dependent protease and that a CAPN11 selective compound is defined as a compound that selectively blocks the activity of CAPN11 at least 10-fold. Methods for detecting protease activity are known in the art. Thus, a method of identifying an inhibitor, as recited in Claims 4 and 5, is disclosed.

This is the same argument presented in the prior response and is not found to be persuasive for the reasons set forth in the prior action.

Art Unit: 1652

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to reject amended claims or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

Art Unit: 1652

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652